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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/016,849	12/14/2001	Jason P. McDevitt	03768/09630	7436

7590 06/02/2004

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EXAMINER	
LEWIS, KIM M	

ART UNIT	PAPER NUMBER
3743	

DATE MAILED: 06/02/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/016,849	MCDEVITT ET AL.	
	Examin r	Art Unit	
	Kim M. Lewis	3743	

-- The MAILING DATE of this communication appears on the cov r sheet with the correspond nce address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 March 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-5,10-29 and 32* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5,10-29 and 32* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *3/11/2004*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: *Detailed Action*.

DETAILED ACTION

Response to Amendment

1. The amendment filed on 3/10/04 has been received and made of record. As requested, claims 6-9, 30 and 31 have been canceled and claims 1-5, 15, 19, 20 and 24-28 have been amended.

2. Claims 1-5, 10-29 and 32 are pending in the instant application.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

5. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein

were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

6. Claims 1, 2, 4, 5, 15, 16,18-21, 23-25, 27-29 and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,156,334 ("Meyer-Ingold et al.") in view of WO97/07273 ("Ninagawa").

As regards claims 1, 2, 19, 24 and 25 and Meyer-Ingold et al. substantially disclose the instant invention. Meyer-Ingold et al. disclose wound coverings for removal of interfering factors from wound fluid. The invention is achieved by covalently bonding substances (enzymes, proteins, etc. (col. 2, lines 51-60)) that interact (*i.e.*, remove or eliminate) with interfering factors (proteases) present in wound exudates to a carrier material. Meyer-Ingold et al. further disclose the use of growth factors in combination with the interfering factors in order to improve the healing process of chronic wounds (col. 3, lines 26-34). Specifically, Meyer-Ingold et al. disclose that wound dressings (*e.g.*, dressing gauze, bandages, compresses, cotton-wool, patches, foil, *etc.*) known in the prior art can be modified by covalently bonding the trapper molecules thereto and simultaneously applying would healing promoting substances such as protein containing growth factors (col. 5, line 1-col. 10, line 4) in the wound.

As to the method, although the steps are not explicitly stated, the process of making the disclosed wound dressing and then applying the wound dressing to a user

reads on the steps of the instant invention. Additionally, the "trapper molecules" are ***capable*** of withdrawing, entrapping and removing a protease from the wound site.

Meyer-Ingold et al. fail to teach that the carrier material (wound dressing) consists essentially of protein fibers. However, Ninagawa discloses the use of a surgical gauze prepared from short silk fibers.

It would have been obvious to one having ordinary skill in the art to select the surgical gauze of Ninagawa, which consists of silk (protein) fibers, as the carrier material for since Meyer-Ingold et al. disclose that wound coverings known in the prior art can be modified and used in the invention.

As regards claims 4, 5, 27 and 28, the protein containing fibrous component is a silk fabric (gauze).

As regards claims 15 and 20, Meyer-Ingold et al. disclose at col. 9, line 65-col. 10, line 4 that the wound healing substances, such as for example, growth factors can be applied into the wound, thereby being separate from the wound dressing.

As regards claims 16 and 21, Meyer-Ingold et al. fail to disclose that the growth factor is in form of an ointment, lotion, solution or gel. Absent a critical teaching and/or a showing of unexpected results derived from the use of a growth factor in the form of an ointment, lotion, solution or gel, the examiner contends that the form of the growth factor is an obvious design choice, which does not patentably distinguish applicant's invention.

As regards claims 18, 23 and 32, note col. 10, lines 1-2, which discloses the use of PDGF (platelet derived growth factor).

As regards claim 29, Meyer-Ingold discloses that the wound dressing further comprises a non-protein-containing component in addition to the protein-containing component (col. 8, line 1-col. 10, line 6).

7. Claims 1, 3, 24 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Meyer-Ingold et al. in view of U.S. Patent No. 5,447,505 ("Valentine").

As regards claims 1, 3, 24 and 26, Meyer-Ingold et al. substantially disclose the instant invention. Meyer-Ingold et al. disclose wound coverings for removal of interfering factors from wound fluid. The invention is achieved by covalently bonding substances (enzymes, proteins, etc. (col. 2, lines 51-60)) that interact (*i.e.*, remove or eliminate) with interfering factors (proteases) present in wound exudates to a carrier material. Meyer-Ingold et al. further disclose the use of growth factors in combination with the interfering factors in order to improve the healing process of chronic wounds (col. 3, lines 26-34). Specifically, Meyer-Ingold et al. disclose that wound dressings (*e.g.*, dressing gauze, bandages, compresses, cotton-wool, patches, foil, *etc.*) known in the prior art can be modified by covalently bonding the trapper molecules thereto and simultaneously applying would healing promoting substances such as growth factors (col. 9, line 57-col. 10, line 4) in the wound. Additionally, the "trapper molecules" are ***capable*** of withdrawing, entrapping and removing a protease from the wound site.

As to the method, although the steps are not explicitly stated, the process of making the disclosed wound dressing and then applying the wound dressing to a user reads on the steps of the instant invention.

Meyer-Ingold et al. fail to teach that the carrier material (wound dressing) consists essentially of protein fibers. However, Valentine discloses the use of wool, gauze, unmedicated cotton, *etc.* (col. 1, lines 9-15) as being a material used to treat wounds, thereby being a dressing.

It would have been obvious to one having ordinary skill in the art to select the wound treatment material of Valentine, which consists of wool (protein) fibers, as the carrier material for since Meyer-Ingold et al. disclose that wound coverings known in the prior art can be modified and used in the invention.

8. Claims 1, 10-14, 17, 19 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent Publication 2002/0064551 ("Edwards et al.") in view of Ninagawa and U.S. Patent No. 5,158,555 ("Porzilli").

As regards claims 1, 19 and 22 Edwards et al. disclose a method for sequestering or inhibiting protease at a wound site that substantially reads on the claimed invention. Edwards et al. specifically, disclose wound dressings of the formula x-a (x bonded to a), wherein x and a are selected from a long list of materials. Included in the list of materials are cotton cellulose formed as woven or nonwoven gauze and proteins (para. 44), which are capable of removing a protease from a wound site once applied (abstract, paragraph 31, and page 3).

Edwards et al. fail to teach the step of selecting a protein-containing fibrous component which consists essentially of protein fibers and forming a wound dressing from the protein-containing fibrous component. However, Ninagawa discloses the use fibers, which consist of silk protein, in making surgical gauze.

In view of Ninagawa, it would have been obvious to one having ordinary skill in the art to modify Edwards et al. by using silk gauze as the carrier material because it is soft and does not damage internal tissues.

Edwards et al. also fail to teach selecting at least one protein from the group consisting of growth factors, cytokines, and chemokines for application to the wound site. However, Porzilli discloses a wound dressing comprising a protein containing a protein fibrous component and an epidermal growth factor (inherently a protein) in order to heal a wound quickly.

In view of Porzilli, it would have been obvious to one having ordinary skill in the art to modify the method disclosed in Edwards et al. with the additional step of adding a protein containing growth factor to the wound dressing in order to heal a wound quickly.

As to step d), applying the wound dressing and protein to the wound site so that the protein-containing fibrous component is in contact with the wound site, the applicant should note that Edwards et al. disclose applying the carrier material with the interfering factors on a wound. The examiner contends that the application of the carrier material with the interfering factors on the wound intrinsically accomplishes applicants' step d).

As regards claims 10-14, since the applicants disclose wound dressings consisting essentially of the same material (*e.g.,* silk protein), the modified wound

dressing of Edwards et al. is also capable of removing proteases which comprises elastase, neutrophil elastase, gelatinase, gelatinase B (MMMP-9) and plasmin, since the applicants have not chemically or physically altered the protein fibrous material in any manner distinguishing it over silk fiber dressing of Ninagawa.

As to the claim 17, a, which is bonded to the carrier material (dressing) is capable of being a protein (para. 44).

Response to Arguments

9. Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kim M. Lewis whose telephone number is 703.308.1191. The examiner can normally be reached on Mondays to Thursdays from 5:30 am to 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry A. Bennett can be reached on 703.308.0101. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Kim M. Lewis
Primary Examiner
Art Unit 3743

kml
5/24/04